RESPONSE TO COMMENTS

External Peer Review of the Updated PCB Exposure Estimation Tool and Exposure Levels for Evaluating (ELEs) PCBs in Indoor School Air

Peer Reviewers:

Robert F. Herrick, Ph.D.
Keri C. Hornbuckle, Ph.D.
P. Barry Ryan, Ph.D.

Contract No. EP-C-17-023
Task Order 68HERH19F0344

Peer Review Conducted for:

U.S. Environmental Protection Agency
Office of Research and Development,
Center for Public Health and Environmental Assessment
MD B243-01
Research Triangle Park, NC 27711

Conducted by:

Versar, Inc.
6850 Versar Center
Springfield, VA 22151
Review completed: November 8, 2019

TABLE OF CONTENTS

I. INTRODUCTION

Versar, Inc. (Versar), an independent Environmental Protection Agency (EPA) contractor, coordinated an external letter peer review of the Updated PCB Exposure Estimation Tool and its use in selecting Exposure Levels for Evaluating (ELEs) PCBs in Indoor School Air. The peer review was conducted for EPA's Center for Public Health and Environmental Assessment (CPHEA), Office of Research and Development (ORD).

In 2009/2010 EPA developed the PCB Exposure Estimation Tool which was used to select ELEs for PCBs in Indoor School Air. The air ELEs were developed for various age groups typically exposed within a school building (i.e., preschoolers, kindergarteners, elementary, middle and high schoolers, and adult staff). These values represent the maximum PCB air concentration that would not result in an exceedance of the RfD for PCB Aroclor 1254, considering background exposures from other school and non-school pathways. The current ELEs for indoor school air are available at https://www.epa.gov/pcbs/exposure-levels-evaluating-polychlorinated-biphenyls-pcbs-indoor-school-air. The ELEs for air are not meant to be interpreted or applied as "bright lines" or "not-to-exceed" criteria. Rather, air measurements above these levels are intended to suggest the need for the further investigation of PCB sources in school building and/or potential actions to reduce exposure.

Recently, the PCB Exposure Estimation Tool was updated to include more recent data on background concentrations of PCBs in environmental media and updated exposure factors from the EPA's Exposure Factors Handbook: 2011 Edition and its 2017 updates. The purpose of this peer review was to solicit written comments from individual experts on EPA's revised PCB Exposure Estimation Tool (Version 2.0) and its use in selecting updated ELEs for PCBs in indoor school air.

Versar selected three senior scientists with broad experience and demonstrated expertise in the area of human health exposure assessment/risk and familiarity with PCBs. The list of the three peer reviewers who participated in this peer review is provided below.

Peer Reviewers:

Robert F. Herrick, Ph.D.
Harvard School of Public Health (retired)

Keri C. Hornbuckle, Ph.D.
University of Iowa

P. Barry Ryan, Ph.D.
Emory University

II. CHARGE TO PEER REVIEWERS

When providing comments, reviewers were encouraged to suggest specific alternatives or additions that they felt would improve the tool.

Charge Questions:

1. Please comment on the utility and functionality of the PCB Exposure Estimation Tool.

2. Please comment on the updated background concentrations used for PCBs in various exposure media (e.g., soil, dust, non-school air) for estimating exposure and developing the ELEs. Are you aware of any data that would better represent background PCB concentrations in these media?

3. Please comment on the input exposure assumptions (e.g., exposure factors) for estimating exposures, and use of the toxicity reference value (i.e., RfD for 1254) for calculating the ELEs for indoor school air.

4. Please comment on the appropriateness of the calculations used for estimating exposures and calculating the ELEs for indoor school air.

5. Please comment on the documentation provided in the PCB Exposure Estimation Tool (Tabs A through K). Does the Tool provide an adequate level of transparency to allow users to see how the calculations are performed and what data are used in the calculations?

6. Please comment on the process used to update the Tool and its transparency, as described in the document entitled *Systematic Review for Updating the Polychlorinated Biphenyl (PCB) Exposure Estimation Tool and the Exposure Levels for Evaluating PCBS in Indoor School.*

Peer Review Monitoring

During the review, two reviewers posed some clarification questions about the revised PCB Exposure Estimation Tool (Version 2.0) to Versar which required detailed responses from EPA. EPA provided additional files requested by the reviewers including a copy of the spreadsheet currently used, the "original" PCB Exposures Estimation Tool for reference, and an FDA memorandum. The exchange of information between the reviewer and EPA was facilitated by Versar, with no direct communication between the two parties. The questions, responses, and additional files were distributed to all reviewers to consider in preparing their written comments.

Following the review, EPA requested that one reviewer elaborate on his initial response to Charge Question 2, where he stated, "It would be useful to compare the results from output from the Tool with an exposure and risk numbers determined in any current studies." EPA was especially interested in knowing specifically what types of studies the reviewer was recommending that they compare with the Tool output. The reviewer provided additional information to clarify his initial response. Versar provided this information to EPA and EPA had no further questions. The exchange of information between the reviewer and EPA was facilitated by Versar, with no direct communication between the two parties.

III. PEER REVIEWER COMMENTS AND EPA RESPONSES BY CHARGE QUESTION

General Impressions
Reviewer comment, Robert F. Herrick: Overall, I commend EPA for updating the PCB Exposure Estimation Tool and Exposure Levels for Evaluating (ELEs) PCBs in Indoor School Air. I find that the information has been presented accurately, and for the most part, clearly. I have some comments and suggestions on the presentation, these are included in the sections below. I hope that EPA will take this opportunity to state as clearly and forcefully as possible that users of the tool should not assume that PCB concentrations in dusts and soils in and around PCB-containing schools are the same as the background levels in average homes or other buildings without elevated PCBs. There are abundant data that buildings with elevated air PCB levels also have elevated dust and soil PCB levels. I have described these data in the sections below. As to the soundness of the conclusions, I have some reservations that again are presented in detail below. In summary, I have reservations on three general aspects: the overall approach to addressing exposures from the air and dust routes; the use of exposure values that are presented with one significant figure; and the way in which the supplemental information was included in the process. **EPA response:** Responses to these general comments are provided below, where the comments are repeated in more detail.
Reviewer comment, Keri C. Hornbuckle: I commend EPA for continuing to provide useful guidance to parents, schools and communities who want to reduce exposure to PCBs. This guidance is under intense demand, in part because of the growing realization that many schools still contain these compounds long after they were banned from sale. Every parent expects the school to be a safe place for their child. It is very disappointing to learn that the school environment may be contaminated with this set of infamous carcinogens. EPA is a critical advisor in this situation and must be able to provide evidence-based guidance for helping parents, schools and communities. Estimating the potential or actual exposure to PCBs for a population is difficult and fraught with an extremely large set of uncertainties. The difficulty lies in the assumptions that must be made about how people are exposed and the levels of contamination in their environment. The uncertainty in these assumptions is very difficult to quantify. Yet, that is what the EPA Tool has done. The Tool is designed to make those assumptions clear and use all available data to reduce the uncertainties associated with those assumptions. The central outcome of the tool is guidance in the form of PCB air concentrations that parents schools and communities can use to evaluate the concentrations in their schools (Exposure Levels for Evaluating (ELEs) PCBs in Indoor School Air). Overall, I find the tool to be well developed, strongly linked to peer-reviewed reports, and to use scientifically valid datasets as the basis of the calculations. I find the most difficult aspect is the uncertainty due to lack of data. This is the main challenge the tool is trying to work around. The most important data needed are the air concentrations from the school in question. If these measurements have been made, then the tool provides a way for schools to decide if the levels

General Impressions
they measured are of concern or not. This is a worthy goal for this EPA tool, and I am very grateful that it has been prepared. I find the tool to be appropriate for this use, to use the most up to date data available, and to be clear in how it came to the ELE values. It is accurate, clear, and the conclusions are sound. **EPA response:** No revision is required to address this reviewer's comment.
Reviewer comment, P. Barry Ryan: The PCB Exposure Assessment Tool (the Tool) is a well-designed, well-organized, and mature software interface affording the user some flexibility in entering data for examination of exposure scenarios of particular interest. The focus of Version 2.0 is on PCB exposures experienced by school-aged young people whose principal exposure is in school settings including daycare, elementary school, and high school. Further, the system also models adults who work within the school building. The Tool is MS Excel based and consists of a number of worksheets coupled together to produce these estimates. There is a significant amount of current hard data encoded into the worksheets to ensure adequate estimates can be made. The Tool is well laid- out with various worksheets color-coded to identify Introduction, Background, Instructions, etc., making the system fairly easy with which to work with minimal start-up time. In particular, the Introduction and Background worksheets supply sufficient introductory material affording the user the context for the Tool as well as an understanding of its utility and implementation. They are featured prominently as the first two worksheets in the workbook. This is a strength the first time one uses the system, but may be annoying in the long run as, once read, it is not likely to be read again, yet they will be there as the leading worksheets all the time the system is used. The Tool itself does seem adequate for what is was designed to do, namely supply central-tendency estates of exposure and risk for PCBs in children attending schools. However, it could be made more flexible. For example, it could more readily allow for parameter modification so that the Tool could be used for other scenarios, e.g., exposure from caulking scenarios in buildings. Again, as indicative by its name, the Tool was developed for this particular- and important scenario- and is good for what it was designed to do. Nevertheless, such modifications would not be difficult to implement and would make the Tool more useable. The authors have performed a relatively complete literature review to find new and useful parameters modified by the literature extant since the last update. The data used appear to be up-to-date as of the end of calendar 2018. However, the updated measures of central tendency showed little modification since V 1.2 suggesting that exposure and risk estimates determined by the Tool V 2.0 are not likely to differ in any qualitative way from early versions. The instructions, as noted in the "How to Run…" tab are adequate and afford use of the Tool by the novice. Modification of parameters is relatively straightforward and should offer little difficulty for the user familiar with spreadsheet programs in general and MS Excel in particular. While I believe that USEPA doubtless wants some consistency in the results that come out of the Tool, the restrictions placed on the user with regard to modification of certain "fixed"

General Impressions
parameters may be overly restrictive. Alternative scenarios may be of interest in which such parameters are modified to address either changes in the systems investigated or breakdown of basic assumptions, e.g., failure of a ventilations system or installation of new PCB-containing materials such as old caulk. The Tool appears to be completely deterministic in its implementation with a focus on central tendencies in distributions of exposures and risks. While these are useful, it may be of interest to examine other parts of the distribution of these important parameters. There are add-ins for MS Excel, e.g., @Risk, Crystal Ball, etc., that offer the use of distributional characteristics for many parameters. It would be of use for USEPA to explore a more sophisticated Tool that allowed for such modifications thereby affording exploration of upper end exposure and risk in reasonable scenarios found in typical schools. This would make the Tool much more valuable to scientists and risk assessors interested in addressing problem scenarios and control strategies. **EPA response:** The reviewer suggests that the flexibility of the Tool could be increased to allow it to be used for scenarios other than that for which it was intended. Although modifications could be considered in the future to broaden the utility of the Tool, Version 2.1[1] will be available to meet the present need for a method to address exposures to PCBs in indoor school air under the most common circumstances. The reviewer also provides arguments in favor of a probabilistic approach for determining outcomes of exposure and risk. It is true that a probabilistic approach could be useful for understanding the full range of potential exposures and for identifying the most critical site-specific data to be collected for minimizing uncertainty. Although efforts toward implementation of a probabilistic approach could be considered in the future, there is a present need for information to address exposures to PCBs in indoor school air, and Version 2.1 will provide a useful resource. In the meantime, the ability to adjust input parameters based on site-specific data provides a mechanism for reducing uncertainty in exposure estimates at a given site beyond what would be possible by a probabilistic approach incorporating information on variability based on nationwide background exposure data.

[1] Version 2.1 of the PCB Exposure Estimation Tool includes revisions in response to these reviewers' comments on Version 2.0.

Charge Question 1

Please comment on the utility and functionality of the PCB Exposure Estimation Tool.

Reviewer comment, Robert F. Herrick:

The EPA guidance at https://www.epa.gov/pcbs/exposure-levels-evaluating-polychlorinated-biphenyls-pcbs-indoor-school-air states that in cases where PCB concentrations in a school's outdoor soils or indoor dusts are greater than those in non-school environments, then school indoor air concentrations would need to be decreased to maintain overall exposure below the RfD. I would say that the current knowledge about the relationship between air PCB levels in buildings and indoor dust levels indicates that elevated PCB dust levels are very likely when air levels above background are present. This has been reported by a number of investigators, and the best information is from EPA itself in the report Polychlorinated Biphenyls (PCBs) in School Buildings: Sources, Environmental Levels, and Exposures by Thomas, et al., EPA/600/R-12/051. US EPA, September 2012. The following table from that report clearly documents this:

Table 4-17. Summary of environmental media total PCB measurement results for six schools[a]

				Total PCB Levels[b,c]		
Environmental Medium (units)	N[d]	% > QL[e]	Mean QL	Median	Inter-Quartile Range	Overall Range
Indoor Air (ng/m^3)	64	77	47	318	59.4 - 732	<QL - 2920
Indoor Surface Wipes (µg/100cm^2)						
High-contact surfaces	72	62	0.100	0.147	<QL - 0.330	<QL – 2.84
Low-contact surfaces	78	80	0.100	0.201	0.128 - 0.419	<QL – 2.30
Indoor dust (ppm)	7	100	3.0	22.0	16.6 - 53.4	11.6 – 86.8
Outdoor Soil (ppm)						
0.5' from building; 0 – 2" soil depth	99	48	0.5	<QL	<QL - 2.13	<QL - 211
3' from building; 0 – 2" soil depth	102	28	0.5	<QL	<QL - 0.548	<QL – 20.6
8' from building; 0 – 2" soil depth	105	21	0.5	<QL	<QL - <QL	<QL – 5.28
Outdoor Air (ng/m^3)	6	0	47	<QL	<QL	<QL

[a] Air, wipe, and soil measurements at six schools; dust measurements from one school.
[b] Reported as total PCBs from Aroclor measurements.
[c] When duplicate samples were collected, the average of the duplicates was used.
[d] Number of samples.
[e] Quantitation limit.

Corner (2002) reported elevated dust PCB levels (up to 5.4 ug/g for the sum of 7 congeners) in buildings where elevated air levels were measured. Coughlan (2002) also found elevated dust PCB levels (up to 81 ppm or ug/g) where air PCB levels were above background. Several investigations of schools in Lexington, MA; Westport, MA; Hartford, CT, and Malibu, CA reported PCB air and dust levels above background. Although these investigations did not result in peer-reviewed publications, there is no reason to doubt the validity of their findings. Finally, I recently reviewed a Danish study that reported good correlation between air and dust PCB levels in apartment buildings. This manuscript should be published in the near future.

Charge Question 1 ***Please comment on the utility and functionality of the PCB Exposure Estimation Tool.***
I would say in summary that the likelihood is very high that schools with elevated PCB indoor air levels also have PCB indoor dust and probably soil levels above background. This information should be included in the exposure assessment strategy and the use of the estimation tool. My comment, then is that the utility and functionality of the tool would be improved by advising potential users of the tool that they need to consider several PCB sources in estimating total PCB exposures in schools. This should be stated explicitly in the Introduction Tab A. In Tab B, users should be advised that the use of the tool in the contaminated school scenario should incorporate actual measurements of PCB levels in indoor dust and soil for the school(s) being assessed. In Tab C How to Use the PCB Exposure Assessment Tool, users should be advised that school buildings that have elevated PCB levels in indoor air typically also have elevated indoor dust and soil PCB levels. In order to accurately estimate total PCB exposures, site-specific input values for dust and soil should be used. Here and elsewhere EPA could provide links to methods for making such measurements. **EPA response:** Text to address this comment has been added to the Inputs & Assumptions tab (Tab D). Specifically, text was added to cells K16 and K17 to highlight the potential for site-specific dust and soil data to be used to inform assessments in schools with elevated PCB concentrations in indoor air. In Version 2.1 of the Tool[1], the "Assumptions" given for the parameter C_{dust} in schools (cell K16) have been revised to read as follows: *Values are set equal to background concentrations but can be changed by the user to reflect school-specific concentrations or relevant values from the literature. PCB levels in dust have been observed to be elevated in buildings with indoor air PCB concentrations above background (U.S. EPA, 2012). Thus, in cases where there is concern about potentially elevated levels of PCBs in air, it may be informative to use site-specific input values for PCBs in dust.* Also, the "Assumptions" given for the parameter C_{soil} in schools (cell K17) have been revised to read as follows: *Values are set equal to background concentrations but can be changed by the user to reflect school-specific concentrations or relevant values from the literature. PCB levels in soil have been observed to be elevated near buildings with indoor air PCB concentrations above background (U.S. EPA, 2012). Thus, in cases where there is concern about potentially elevated levels of PCBs in air, it may be informative to use site-specific input values for PCBs in soil.* Other tabs were not modified: The Introduction tab (Tab A) provides a general overview of the purpose and organization of the Tool. Including information about specific input values to maintain/modify would not match the level of detail presented in this section of the Tool. The Background tab (Tab B) provides background information on the Tool, including the exposure

Charge Question 1 ***Please comment on the utility and functionality of the PCB Exposure Estimation Tool.***
scenarios addressed and the assumptions used for estimating exposures, focused mostly on exposure factors rather than environmental PCB concentrations. The How-to tab (Tab C) provides information on how to navigate through the Tool and to work with the information within it; it is targeted especially toward users with limited experience with Microsoft Excel. Tab D provides input values and assumptions for each parameter used in the Tool and was selected as the most appropriate section of the Tool to modify in response to this reviewer's comment.
Reviewer comment, Keri C. Hornbuckle: General Comments: Because the tool is not released publicly, I assume it is designed primarily for EPA personnel. I do not know exactly how an EPA staff member would respond to a question about PCBs in a particular school. According to EPA: "The ELEs were derived to serve as health protective values intended for evaluation purposes. They should not be interpreted nor applied as "bright line" or "not-to-exceed" criteria but may be used to guide thoughtful evaluation of indoor air quality in schools." This stated goal is not consistent with the method used by the tool, which produces a single number that cannot be interpreted as anything but a 'bright line'. The tool is designed to provide a single number, and that is scientifically and statistically indefensible. Instead, the tool should provide a range of probable values. The tool should not make calculations with a single number but should use a stochastic approach and calculate probabilities. The benefit of a stochastic approach is that the user can more easily determine what is the most uncertain part of the equation. Use of probabilities to define the range could help EPA and schools decide what additional data to collect. I encourage EPA to refine the tool in future versions to include quantitative measures of uncertainty for every value. That said, I can understand why a single value is helpful. Especially if schools collect air samples that are analyzed for PCBs in a manner that allows them to compare their levels to this single value. I encourage EPA to help schools make this measurement. If EPA cannot pay for the measurement, it would be valuable for EPA to encourage collection of the measurement and provide advice about methods for collecting airborne PCB data. Knowing the actual level of PCBs in school air will provide the most important information. Without actual school air values, this ELE tool is useless. I would like to see EPA assist schools in getting accurate measurements for their own facilities. **Minor comment:** I recommend reordering the tabs so that the calculations refer to cells in tabs previously presented. For example, total exposures should be in a tab after the calculations for background and school exposures are presented. **EPA response:** The reviewer provides arguments in favor of a probabilistic approach for determining outcomes of exposure and risk. It is true that a probabilistic approach could be useful for understanding the full range of potential exposures and for identifying the most critical site-specific data to be collected for minimizing uncertainty. Although efforts toward implementation of a probabilistic approach could be considered in the future, there is a present need for information to address

Charge Question 1 ***Please comment on the utility and functionality of the PCB Exposure Estimation Tool.***
exposures to PCBs in indoor school air, and Version 2.1 of the Tool[1] will provide a useful resource. In the meantime, the ability to adjust input parameters based on site-specific data provides a mechanism for reducing uncertainty in exposure estimates at a given site beyond what would be possible by a probabilistic approach incorporating information on variability based on nationwide background exposure data. The tabs are presented in the following order: • Inputs & Assumptions (Tab D). This tab provides input values and assumptions for the parameters used in the Tool. It is also the tab used for changing input values. When alternate values are entered in this tab, the calculations in Tabs E, F & G are updated. • Total Exposure (Tab E). This tab shows the total PCB doses from each pathway evaluated (e.g., inhalation of indoor air, ingestion of dust, etc.). When a user enters alternate values in Tab D, the primary results of the analysis are shown in this tab. These results are most likely to be of most interest to the user. Therefore, the tab order in Version 2.0 of the Tool was selected to facilitate access to the analytical results of most interest. Tabs F & G are provided to maximize transparency, but they might not be of interest to every user and should not be promoted to a position before this tab. • Background Exp (Tab F). This tab calculates background doses of PCBs from non-school dust and soil ingestion, inhalation of indoor and outdoor air, dermal absorption, and dietary ingestion (food). The results presented in this tab represent one component of total exposure, which is shown in Tab E. • School Exp (Tab G). This tab calculates PCB doses that could occur in schools. Estimates are provided for dust ingestion, soil ingestion, inhalation of indoor school air and surrounding outdoor air, and dermal absorption. The results presented in this tab represent one component of total exposure, which is shown in Tab E.

Charge Question 1 ***Please comment on the utility and functionality of the PCB Exposure Estimation Tool.***
Reviewer comment, P. Barry Ryan: In general, I found the Tool to be useful as a simple tool to address that for which it was designed, namely developing a deterministic approach to estimating exposure and risk associated with PCB exposures in schools and among school-age populations and those working in such environments. Further, while I did not explore every possible combination of changes to parameters, it appears to be functional in its approach end implementation. As a Tool, it is efficient in developing guidelines for exposure. As one shortcoming, I note the reliance on a deterministic approach for determining outcomes of exposure and risk. The focus on central tendencies in these outcomes can be overcome thorough judicious choice if input parameters to estimate, say, the 90th percentile of likely concentrations and concomitant exposures and risk. However, this is cumbersome and would require some work on the part of the user. Again, as a screening tool, the Tool maybe adequate and useful for the intended user. It is quite functional but restricted in its use to very- perhaps overly- restrictive scenarios. **EPA response:** Please see EPA response to this reviewer's comments regarding the advantages of a probabilistic approach under "General Impressions" above.

Charge Question 2

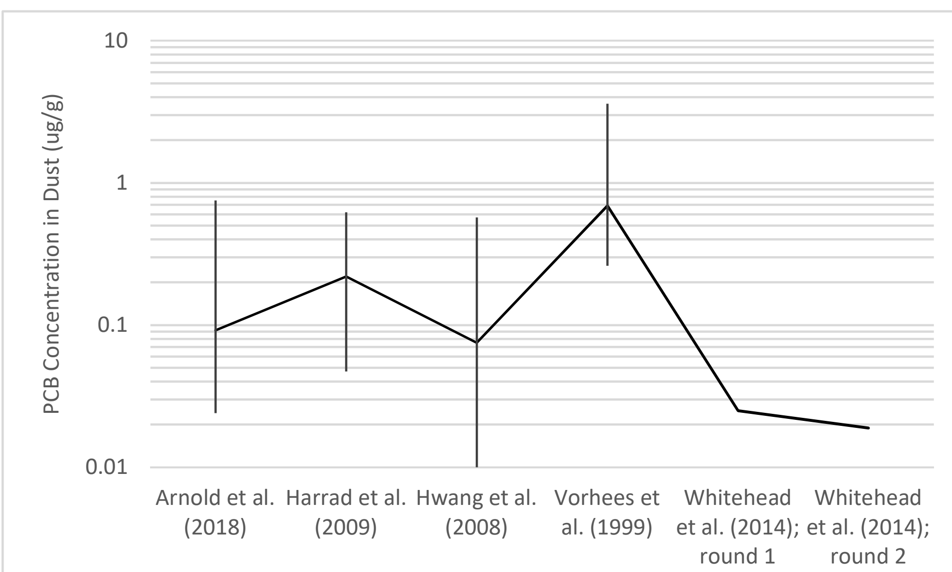
Please comment on the updated background concentrations used for PCBs in various exposure media (e.g., soil, dust, non-school air) for estimating exposure and developing the ELEs. Are you aware of any data that would better represent background PCB concentrations in these media?

Reviewer comment, Robert F. Herrick:

The background information on PCB levels in dust is sparse (9 studies total: 3 Yes, 1 Already in Tool, 5 Supplemental). There is a study by Whitehead however (Environ. Sci. Technol.48: 157−164.) which presents congener-specific data in Table 1 (Summary statistics for PCB measurements in dust collected during two rounds from 289 residences in the California Childhood Leukemia Study, 2001– 2007 and 2010). It would be possible to sum the median values for the 15 congeners presented to get a reasonable value of total PCB in dust.

EPA response:

Whitehead et al. (2014) was not selected for use in the Tool because it presented PCB measurements by individual congener rather than as a measure of total PCBs. Even if the concentrations of the 15 congeners measured by Whitehead et al. (2014) are summed, it is expected that the resulting value would underestimate the total PCB concentration because so many congeners are not represented in the analysis. In the chart below, median dust PCB concentrations derived from those reported by Whitehead et al. (2014) (calculated as the sum of the concentrations reported for 15 individual PCB congeners in Table 1) are compared with the central tendency values for PCBs in dust reported by the 4 studies used in the Tool (Arnold et al. 2018; Harrad et al. 2009; Hwang et al. 2008; Vorhees et al. 1999). The vertical lines indicate the range of values observed in each study; a range for total PCB concentrations cannot be calculated for Whitehead et al. (2014) based on the way the data are reported in that study.



As expected, values derived from the study by Whitehead et al. (2014) are generally lower than the values reported by the other studies, which measured larger numbers of congeners (≥

Charge Question 2 ***Please comment on the updated background concentrations used for PCBs in various exposure media (e.g., soil, dust, non-school air) for estimating exposure and developing the ELEs. Are you aware of any data that would better represent background PCB concentrations in these media?***
54). Since the Tool is intended to estimate exposure to total PCBs and use of this study's data would tend to underestimate exposure, this study was excluded from the analysis.
Reviewer comment, Keri C. Hornbuckle: I commend EPA on the exhaustive and comprehensive literature search. I am very impressed with the quality of this search and see that all available data have been used to improve the quality of the tool. It is remarkable that so few papers met the requirements for use in the tool. In the case of PCB concentrations in food, it appears that there are NO peer-reviewed reports appropriate for use in the tool. Therefore, the estimations of exposure to PCBs through diet is highly uncertain. It is not clear why Ampleman et al. (2015) dietary data could not be used. The data used by the EPA tool has not been peer reviewed and is not publicly available for quality assessment. For example, the dietary intake for a preschool child is estimated at 0.002 micrograms per kilogram per day, a value that has no basis in the peer reviewed literature. In this and similar cases of scarce data that is required by the tool, it is hard to justify a single number choice. I again recommend EPA develop the next version of the tool to use a range that reflects this uncertainty. There are scientific data about food that EPA chose not to use. For example, it is established with plentiful data that PCBs are more likely to be in fish than in beef. Therefore, a school population from a community that eats more fish should not estimate their exposure levels the same a school population from a community that does not eat much fish. In future versions of the tool, EPA may want to consider an input that captures these dietary differences. My laboratory has recently completed a study of PCBs in food frequently consumed by our cohort communities in northwest Indiana and rural Iowa. We expect to publish this report and associated data this winter or early spring. My laboratory has recently compiled the congener-specific air concentrations measured at schools. These data were summarized in Marek et al., 2017. We are releasing the entire dataset this fall. **EPA response:** Dietary data from Ampleman et al. (2015) were not selected for use in the Tool because those data were based on PCB concentrations in foods as reported in older Canadian Total Diet Studies, and the intent of the Tool is to estimate exposures based on the most current U.S. background-level data. The Tool uses dietary PCB data from the U.S. Food and Drug Administration's (FDA's) Total Diet Study (TDS), which is the U.S. government's primary food monitoring program. The TDS involves retail purchases of foods representative of the "total diet" of the average U.S. population, including baby food, beverages, dairy, eggs, fat, oil, fruits, grains, legumes, meat, poultry, fish, sweets, and vegetables. The study also includes the analysis of the foods for levels of specific analytes and estimation of dietary intake of those

Charge Question 2 ***Please comment on the updated background concentrations used for PCBs in various exposure media (e.g., soil, dust, non-school air) for estimating exposure and developing the ELEs. Are you aware of any data that would better represent background PCB concentrations in these media?***
analytes by selected age/sex groups. Information on the TDS, including its history and the methods used for estimating dietary intakes can be found at https://www.fda.gov/food/science-research-food/total-diet-study. Version 2.0 of the Tool used TDS data from 2003, which is the most recent TDS data set for PCBs. According to Spungen (2014) (provided in Tab L of the Tool), "The TDS program no longer includes analysis of total PCBs." To address this reviewer's comment, Version 2.1[1] has been revised to use, instead of the single number from the 2003 TDS dataset, the average dietary intake of PCBs reported by the TDS in 1995, 1997, and 2003. The standard deviation across this period also is reported to provide an indication of the uncertainty and variability associated with this parameter. Furthermore, dietary estimates from outside the U.S. (i.e., from Belgium and Canada) also are presented for comparison. Dietary differences can be accommodated by entering alternate input values for ADD_{food} in the Inputs & Assumptions tab (Tab D). A note in Tab D cell K21 (under "Assumptions" for ADD_{food}) states that "Data represent general population exposures and may not accurately represent populations that regularly consume fish with higher than typical PCB tissue concentrations or populations that consume fish as a greater than average percentage of diet." Marek et al. (2017) was used as a key study in the development of the Tool, especially in the calculation of the background value for $C_{air\text{-}outdoor}$ (air concentration outdoors (ng/m^3)).
Reviewer comment, P. Barry Ryan: The updated concentration data extracted from the more recent literature appears to be comprehensive and reflective of current measures in the field. The calculation of central tendency measures for concentrations in various media reflect little change since V1.2 and hence little change in exposure and risk. While the literature review was extensive, the number of new studies found was very limited. Further, a significant amount- more than half in most cases- was non-US data bringing the applicability to US schools into question. However, the small changes noted from V1.2 to V2.0 suggest that such data, even if not from the US, is reflective of what is currently extant. Further new sources of PCBs in such environments are very limited, if any. Environmental lifetimes for these materials are long and steady-state concentrations in air, dust, and soil have, no doubt, been reached. It would be useful to compare the results from output from the Tool with an exposure and risk numbers determined in any current studies. Such "ground-truthing" would be of interest and add credence to the modeling results. With regard to new data, the only data that I am aware of that might be useful are the Danish studies comparing PCB levels in two sets of apartment complexes. See for example: Frederiksen M, Meyer HW, Ebbehoj NE, Gunnarsen L. Polychlorinated biphenyls (PCBs) in indoor air originating from sealants in contaminated and uncontaminated apartments within the same housing estate. Chemosphere 2012;89:473-9 and other related work. In addition, I do not recall seeing a reference to: Macintosh DL, Minegishi T, Fragala MA, Allen JG, Coghlan KM,

Charge Question 2 ***Please comment on the updated background concentrations used for PCBs in various exposure media (e.g., soil, dust, non-school air) for estimating exposure and developing the ELEs. Are you aware of any data that would better represent background PCB concentrations in these media?***
Stewart JH, et al. Mitigation of building-related polychlorinated biphenyls in indoor air of a school. Environ Health 2012;11:24, although I may have missed it. **Note:** Following the review, Dr. Ryan elaborated on his initial response to Charge Question 2, in response to a clarifying question from EPA: Overall, I think it is important that any study with in-school measurements could be used to evaluate and validate the model and, indeed, any study with indoor measurements of PCBs in setting with similar sources. I am not suggesting anything out of the ordinary. If data are available to check the efficacy of the modeled results in a real-world situation, they should be implemented. EPA should be able to answer questions regarding the accuracy of the model in predicting such exposures and risk. Is the model good within a factor of 10? A factor of 2? Within 10%? Each of these cutoffs supplies useful information, but as the model becomes more accurate, then it becomes more useful in establishing risk to the children and employees in the facility, and suggests the need- or lack thereof- for mitigation strategies. I did supply two references that I thought might be useful. The first of these is an examination of PCB exposures associated with window caulking in two Danish apartment complexes. While not schools, such work may give insight into the variances in exposures associated with older window caulking and newer in indoor settings. Further, the study referenced gives insight as to the lifetime of PCB exposure associated with building materials. The second reference is on point as it looks at PCB exposures in schools directly. I did not see this referenced in the materials I had for review and suggest that it be included in the document and Tool to evaluate its efficacy in predicting measured values. **EPA response:** Frederiksen et al. (2012) was considered for use in the Tool but was ultimately decided to be "supplemental" because the data were drawn from outside the U.S. In Version 2.1 of the Tool[1], supplemental data have been included in Tabs D and M for comparison with U.S. data. "Assumptions" for $C_{air\text{-}indoor}$ (Tab D, cell K13) now contain the following text: *Average of central tendency values (mean and geometric means) from 3 studies that collected indoor air samples from background locations in the U.S.: Ampleman et al., 2015 [mean of geometric means for homes in Indiana (1.0 ng/m^3; n=34) and Iowa (0.44 ng/m^3; n=35), and schools in Indiana (6.4 ng/m^3; n=13) and Iowa (8.4 ng/m^3; n=11); total of 201 congeners]; Fitzgerald et al., 2011 (mean of 176 samples collected from homes in New York based on Aroclors 1242, 1254, 1260 = 14 ng/m^3, range = 0.6 - 233 ng/m^3); and Vorhees et al. (1997); geometric mean of 16 homes in Massachusetts; total of 65 congeners = 10 ng/m^3, range = 5.2 - 51 ng/m^3). A study by Marek et al., 2017 reported a range of 0.5 - 194 ng/m^3 for 6 schools in Iowa and Indiana based on 209 PCB congeners. These values can be changed by the user to*

Charge Question 2 ***Please comment on the updated background concentrations used for PCBs in various exposure media (e.g., soil, dust, non-school air) for estimating exposure and developing the ELEs. Are you aware of any data that would better represent background PCB concentrations in these media?***
reflect site-or situation-specific conditions. For comparison purposes, the average background concentration of PCBs in indoor air was also calculated using the average of the central tendency values from both the U.S. studies and supplemental non-U.S. studies (7.2 ng/m^3) (see Tab M for study details). Overall, concentrations reported in the various studies ranged from less than the limit of quantification (LOQ) to 233 ng/m^3. Data from Frederiksen et al. (2012) were included in the calculation using the average of the central tendency values from both the U.S. studies and supplemental non-U.S. studies (7.2 ng/m^3). In addition to providing background concentrations for PCBs in indoor air of uncontaminated apartments in Denmark, Frederiksen et al. (2012) also provides data for contaminated apartments (mean = 1030 ng/m^3, n = 83). If, as the reviewer suggests, this value from Frederiksen et al. (2012) is used in the Tool, it would be most appropriate to enter it in cells D13-J13 of Tab D, which correspond to the background value for $C_{air\text{-}indoor}$ (concentration of PCBs in non-school indoor air). The resulting total exposures would be 597, 529, 453, 309, 225, 191, and 133 ng/kg/day for ages 1 to <2, 2 to <3, 3 to <6, 6 to <11, 11 to <15, 15 to <19 years, and adults, respectively, with 98.3-99% of the total exposure coming from indoor air inhalation outside of school. All of these values are well above the RfD of 20 ng/kg/day and would indicate some level of concern regarding potential health effects of PCB exposure. Frederiksen et al. (2012) notes that "In Denmark, the National Board of Health (NBH) has issued two 'recommended indoor air limits as a threshold for action' based on a toxicological reference dose of PCB_{tot}…The lower limit is 300 ng m^{-3} for PCB_{tot} in air; if this is exceeded, NBH recommends that action is taken to reduce the level." 300 ng/m^3 is comparable to the PCB ELEs derived using Version 2.1 of the Tool, which range from 100-600 ng/m^3 depending on age group. Regarding the reviewer's comments related to "predicting exposures" (e.g., "Is the model good within a factor of 10? A factor of 2? Within 10%?"), it is not possible to answer these questions with the available information. The function of the Tool is not to "predict" exposure but to estimate total exposure based on measurements of PCBs in environmental media. And, when site-specific measurements are not available, the Tool provides default values representative of U.S. background concentrations based on a comprehensive and systematic review of the literature. Frederiksen et al. (2012) does not report measures of total PCB exposure for its study population, which would be needed to compare to the Tool's output in order to assess its accuracy. Furthermore, the utility of the Tool for estimating exposures in populations outside the U.S. is particularly uncertain due to the reliance of the Tool on U.S. background-level data. The inherent uncertainty of the Tool's exposure estimates is acknowledged both in the use of only one significant figure in the derivation of the ELEs and also in the statement that "[The ELEs for air] should not be interpreted nor applied as "bright line" or "not-to-exceed" criteria, but may be used to guide thoughtful evaluation of indoor air quality in schools" (https://www.epa.gov/pcbs/exposure-levels-evaluating-polychlorinated-biphenyls-pcbs-indoor-school-air).

Charge Question 2 ***Please comment on the updated background concentrations used for PCBs in various exposure media (e.g., soil, dust, non-school air) for estimating exposure and developing the ELEs. Are you aware of any data that would better represent background PCB concentrations in these media?***
Macintosh et al. (2012) was identified in the initial literature search but was excluded because it was not considered to be relevant for the Agency's intended use. This study provided data only on a contaminated school building; the PCB concentrations reported are not representative of background concentrations. Macintosh et al. (2012) did provide measurements of PCBs in air before and after implementation of three mitigation measures, and the Tool might be useful to assess the impacts of those mitigation measures on total human exposures to PCBs. At baseline, the median indoor air PCB concentration at the school was 432 ng/m^3 (n = 9). If 432 ng/m^3 were used as the school value for $C_{\text{air-indoor}}$ (concentration of PCBs in school indoor air) in Version 2.1 of the Tool, the resulting total exposures would be 58, 53, 36, 25, 18, 15, and 17 ng/kg/day for ages 1 to <2, 2 to <3, 3 to <6, 6 to <11, 11 to <15, 15 to <19 years, and adults, respectively, with 79-83% of the total exposure coming from indoor air inhalation at school. These values are above the RfD of 20 ng/kg/day for the younger age groups (up to 11 years of age). Especially since the measurements were collected at an elementary school, these results might indicate that further investigation into potential PCB sources and remediation strategies could be useful. Macintosh et al. (2012) reported on the results following three interventions at this school (ventilation, contact encapsulation, and physical barriers), and the reported median air PCB level fell to 76 ng/m^3 (n = 19). If this value were used for school $C_{\text{air-indoor}}$ in Version 2.1 of the Tool, the resulting total exposures would be 18, 17, 13, 9, 6, 5, and 6 ng/kg/day for ages 1 to <2, 2 to <3, 3 to <6, 6 to <11, 11 to <15, 15 to <19 years, and adults, respectively. These results would suggest that the interventions were successful in reducing exposures from PCBs in indoor air; uncertainty in these results might be addressed by gathering information on other site-specific exposures (e.g., from dust and soil at the contaminated school, based on dietary customs and habits of the local population). In this case, the study authors did conduct a site-specific risk assessment for the school to confirm that the remediation efforts adequately mitigated health risk posed by PCBs in indoor air (MacIntosh, DL; Minegishi, T; Allen, JA; Levin-Schwartz, Y; McCarthy, JF; Stewart, JH; Coghlan, KM (no date) Risk Assessment for PCBs in Indoor Air of Schools. http://www.isiaq.org/docs/presentations/1102_MacIntosh.pdf). However, as with Frederiksen et al. (2012), it is not possible to "validate" the Tool using the data presented by Macintosh et al. (2012) because this study did not report measures of total PCB exposure for its study population.

<table>
<tr><th>Charge Question 3
Please comment on the input exposure assumptions (e.g., exposure factors) for estimating exposures, and use of the toxicity reference value (i.e., RfD for 1254) for calculating the ELEs for indoor school air.</th></tr>
<tr><td>Reviewer comment, Robert F. Herrick:
I think the exposure factors and the toxicity reference value are appropriate for use in the tool.

EPA response:
No revision is required to address this reviewer’s comment.</td></tr>
<tr><td>Reviewer comment, Keri C. Hornbuckle:
As noted above, even though highly uncertain, the dietary exposure term could be broken down into its input variables: size of the child/adult, mass of food consumed per day, distribution of food types per category, and PCBs in food type. It would also be good to separate food eaten at school from food eaten at home. Many children consume most of their food at school and so placing this category in the non-school exposure set is misleading. That said, I am sure we don’t know if food in schools has more or less PCBs than food from home, so it does not matter much.

The use of the RfD from 1254 is a reasonable assumption.

EPA response:
As noted above, the Tool uses dietary PCB data from the U.S. FDA’s TDS, which does consider the input variables listed by the reviewer. It is unlikely that an independent effort to develop dietary intake estimates for the general U.S. population would improve upon those developed by the TDS program, which has been the U.S. government’s primary food monitoring program since 1961. However, as the reviewer mentions, estimating dietary PCB intakes is highly uncertain, and there also is a great deal of variability across populations depending on their dietary customs and habits. Although refinements of the Tool that would allow users to enter custom values for variables such as mass of food consumed per day, distribution of food types per category, and PCBs in food type could be considered in the future, there is a present need for information to address exposures to PCBs in indoor school air, and the most relevant data for the general U.S. population have been selected for use in the Tool. In the meantime, users can modify the ADD_{food} input value as needed to address site-specific concerns.</td></tr>
<tr><td>Reviewer comment, P. Barry Ryan:
The various exposure factors used in the Tool were drawn primarily for the Exposure Factors Handbook from 2011 and, thus, are considered to be “state-of-the-science.” However, the EFH is now eight years old and represents thinking perhaps a couple of years before the publication date or ten years ago. These factors may need updating. However, this is not a flaw in the Tool as it is not in the purview of this model development to update the EFH. Any modifications to the EFH would be made elsewhere and could easily be implemented in V 2.01.

Toxicological risk assessment and the determination of an RfD for Aroclor 1254 is not my area of expertise, but to my knowledge, these experiments have been carried out historically and are not likely to be substantially changed- or even repeated- in the near future.</td></tr>
</table>

Charge Question 3 ***Please comment on the input exposure assumptions (e.g., exposure factors) for estimating exposures, and use of the toxicity reference value (i.e., RfD for 1254) for calculating the ELEs for indoor school air.***
EPA response: No revision is required to address this reviewer's comment.

Charge Question 4 ***Please comment on the appropriateness of the calculations used for estimating exposures and calculating the ELEs for indoor school air.***
Reviewer comment, Robert F. Herrick: I think the calculations themselves are appropriate; my comments as stated above are on the importance of using site-specific input values. **EPA response:** No revision is required to address this reviewer's comment.
Reviewer comment, Keri C. Hornbuckle: As noted above, the decision to present the calculations as a linear equation rather than in a stochastic way is misleading. Each assumption could be represented as a distribution of values rather than a single average. Then, instead of allowing the user to just change an average, the user can instead just change the mean and standard deviation of the variable. This would then allow the user to examine which term is most important to define. **EPA response:** Please see EPA response to this reviewer's comments regarding the advantages of a probabilistic approach under "Charge Question 1" above.
Reviewer comment, P. Barry Ryan: The models used to calculate ELEs for indoor school area are standard deterministic exposure modeling equations. They are appropriate in this context for deterministic estimation of measures of central tendency. But please note my early comments proposing a Tool version that allows probabilistic estimates to be done. **EPA response:** Please see EPA response to this reviewer's comments regarding the advantages of a probabilistic approach under "General Impressions" above.

Charge Question 5 *Please comment on the documentation provided in the PCB Exposure Estimation Tool (Tabs A through K). Does the Tool provide an adequate level of transparency to allow users to see how the calculations are performed and what data are used in the calculations?*
Reviewer comment, Robert F. Herrick: I think that in general the documentation in Tabs A-K is adequate and transparent. One possible addition would be to somewhere address the supplemental information that is included in the Update document, is it possible to briefly describe what it is and how it was used? **EPA response:** Version 2.1 of the Tool[1] includes a "Study Summaries" tab to summarize the data from both the studies used to derive U.S. background exposure estimates and "supplemental" studies, which reported background concentrations of PCBs in non-U.S. countries for one or more of the environmental media of interest. Data from the supplemental studies are presented in the "Assumptions" column in Tab D for comparison with the U.S. values.
Reviewer comment, Keri C. Hornbuckle: The tool is easy to use and the relevant citations are well documented. It is well written and transparent. The quality of the literature review and use of available data is excellent. **EPA response:** No revision is required to address this reviewer's comment.
Reviewer comment, P. Barry Ryan: The presentation of the models is transparent and adequate; they are written out explicitly in the worksheets with a separate worksheet describing the meaning for each variable. Further, in the Systematic Review document the methods for determining the papers selected for use as well as the selection of Exposure Factors is delineated. I have no difficulties with this level of transparency. If anything, the volume of the written text and Appendixes is a little bit intimidating. **EPA response:** No revision is required to address this reviewer's comment.

Charge Question 6 ***Please comment on the process used to update the Tool and its transparency, as described in the document entitled Systematic Review for Updating the Polychlorinated Biphenyl (PCB) Exposure Estimation Tool and the Exposure Levels for Evaluating PCBs in Indoor School Air.***
Reviewer comment, Robert F. Herrick: I think the process itself, and the description of the process used to update the Tool and its transparency is clear and appropriate. Is the plan to eventually disseminate this, or something derived from it as a sort of documentation for the Tool? As I mentioned in my first comment, I don't understand the rationale underlying the practice of reporting the exposure levels to one significant figure. I realize that this is the convention used for the exposure factors, although I don't see the reason for this fully explained in the Exposure Factors Handbook (or maybe I missed it?). In any case, I question this practice in the presentation of the Exposure Levels. As EPA says on the PCB website, "The ELEs were derived to serve as health protective values intended for evaluation purposes. They should not be interpreted nor applied as "bright line" or "not-to-exceed" criteria but may be used to guide thoughtful evaluation of indoor air quality in schools." I totally get this and agree, but in practice people do use them exactly this way, basing decisions about what actions to take (or not take) on these numbers. This isn't unique to the values, I have been saying things like this for almost fifty years and it never stops people from using the numbers this way (as bright lines). So given that reality I would suggest using the most exact values for the exposure levels that the data supports. **EPA response:** Although the values used in the Tool are based on a comprehensive and systematic review of the literature and were selected according to specific criteria to ensure their relevance for use in estimating U.S. background-level exposures to PCBs, uncertainty exists for every input value (e.g., background media concentrations, exposure factors, RfD). The definition of the RfD includes an allowance for "uncertainty spanning perhaps an order of magnitude." And as, another reviewer mentioned, "Estimating the potential or actual exposure to PCBs for a population is difficult and fraught with an extremely large set of uncertainties. The difficulty lies in the assumptions that must be made about how people are exposed and the levels of contamination in their environment. The uncertainty in these assumptions is very difficult to quantify." According to U.S. EPA's Guidelines for Exposure Assessment (U.S. EPA, 1992. Guidelines for Exposure Assessment. U.S. Environmental Protection Agency, Washington, DC, EPA/600/Z-92/001. https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=15263), "The number of significant figures should reflect the uncertainty of the numeric estimate. If the likely range of the results spans several orders of magnitude, then using more than one significant figure implies more confidence in the results than is warranted."

Charge Question 6 ***Please comment on the process used to update the Tool and its transparency, as described in the document entitled Systematic Review for Updating the Polychlorinated Biphenyl (PCB) Exposure Estimation Tool and the Exposure Levels for Evaluating PCBs in Indoor School Air.***
Reviewer comment, Keri C. Hornbuckle: The tool is not freely accessible from any link I could find. The tool should be publicly available. **EPA response:** The PCB Exposure Estimation Tool is an important Agency resource, but it was not developed for public use, nor is it intended to be used by the public without guidance from knowledgeable EPA staff or other technical experts. As described at https://www.epa.gov/pcbs/exposure-levels-evaluating-polychlorinated-biphenyls-pcbs-indoor-school-air, "Building owners and school administrators who want to make calculations based on their own specific circumstances should contact their EPA regional PCB coordinator." PCB coordinators provide interested parties with access to the most current version of the Tool and are able to provide guidance on its appropriate use and interpretation of the results.
Reviewer comment, P. Barry Ryan: The Systematic Review document does supply a great deal of detail on how the manuscripts were selected for inclusion and how the data were developed. The approach was quite systematic and the mechanisms by which the search for papers was developed in exceptional detail. However, as indicated in the previous answer, the sheer volume and the presentation is somewhat intimidating. I do note that a significant fraction of this presentation are the summary tables describing each selected paper. I have no clear thoughts on how that might be improved, but I do suggest that the authors give some thought to this process. **EPA response:** The systematic review document was developed to support the peer reviewers' understanding of the process used to update the tool and the ELEs, it is not intended for immediate public release in its current form. However, the reviewer's suggestions will be considered if the decision is made to release the document (e.g., as a peer-reviewed manuscript).

Specific Observations on Version 2.0 of the PCB Exposure Estimation Tool			
REVIEWER	**Tab**	**Cell**	**REVIEWER COMMENT or QUESTION**
Robert F. Herrick	D	16 A-J	When I input a site specific value of 20 ug/g for the PCB content of indoor dust here (based upon the median value of 22 from the EPA investigation of NYC schools presented in the table under my comment #1 above), the tool calculates that the youngest children in the day care group have a total exposure of 30.4 ng/kg-day; the other children under age 6 have much higher totals as well than when the default value for dust (0.27 ug/g) is used. In my opinion, this supports the call that site-specific values be used especially for indoor dust. **EPA response:** Please see EPA response to this reviewer's comments regarding the importance of collecting data on PCB levels in dust and soil at schools with elevated indoor air PCB concentrations under "Charge Question 1" above.
Keri C. Hornbuckle	D	K14	Sentence repeated **EPA response:** The repeated sentence is no longer present in Version 2.1[1].
P. Barry Ryan			I have no specific observations. The worksheets within the Tool are transparent and straightforward to follow. I did not check to see if the various formulas were correctly implemented as I must assume that USEPA did this correctly. **EPA response:** No revision is required to address this reviewer's comment.